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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,450	03/31/2004	Samuel C. Evans		5451

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SAMUEL C. EVANS
457, ARNOLD STREET, NE
ATLANTA, GA 30308

EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/20/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/814,450	EVANS, SAMUEL C.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-20 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for providing disinfection against commonly known pathogens, does not reasonably provide enablement for preventing the transmission of most sexually transmitted diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Enablement is considered in the view of the Wands factors (MPEP 2164.01 (a)). These include the nature of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, and state of the prior art. All of the Wands factors have been considered with the regard to the instant claims, with the most relevant discussed below.

Nature of the Invention: The rejected claims are drawn to the a topical composition comprising 8 to 12 % by wt. of Povidone-Iodine complex, 0.5 to 1.0 % by wt. of potassium iodide, 1 to 10 % by wt. of phosphate, 5 to 15 % by wt. chlorhexidine acetate, 5 to 20 % by wt. of alcohol, 1 to 5 % by wt. of citric acid and the remaining being pharmaceutically acceptable excipients to provide disinfection against commonly known pathogens and prevent transmission of most of the sexually transmitted diseases.

Breath of the claims: The nature of the invention is extremely complex in that it encompasses preventing various STDs with *one* topical composition. Further, the topical composition must either inactivate the virus particles; prevent the virus from attaching to and fusing with the host cells; or prevent the virus from replicating should it succeed in infecting the cells in order to prevent the transmission of the disease. This may or may not be addressed by the administration of the claimed composition.

Guidance of the Specification: The guidance provided by the specification does not reasonably demonstrate that the instant composition *prevents* the transmission of STDs. The mere assertion that the composition prevents transmission of STDs is not sufficient without data or evidence. The specification states that the topical composition provides two important functions to prevent the transmission of the STD: 1) the composition is liquid, it acts as a lubricant, thereby reducing the amount of friction which causes such cuts, and 2) it coats these tiny cuts with a protective action that kills the virus so it cannot infect. However, the term “prevention” is absolute definition, which means to stop from occurring and it is not just the reduction of the potential risk of transmitting (for instance by reducing friction that causes cuts); thus the term requires a higher standard for enablement than a term such as “reducing”.

The State of the Art and Predictability of the Art: Firstly, the state of the art indicates that “the only sure way of preventing STDs and AIDS is through sexual abstinence or a relationship with only one uninfected person. Note page 4 of <http://www.woodtv.com> (attached with the office action). Further, the state of the art indicates that “while condoms do not eliminate risk, the correct use of a condom and avoidance of certain sexual practices can decrease the risk of contracting AIDS, as well as other STDs.” See page 5. Also note the Student

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Health Center pamphlet by the University of Alabama, School of Medicine Tuscaloosa Campus (attached with the office action) which discloses: “[condoms] may not protect against transmission of STDs transmitted through direct skin-to-skin contact....Although not 100% effective, for sexually active people condoms provide the best means of protection available today for STDs. Condoms cannot prevent STD transmission, but they can help reduce the risk.” See page 2. Therefore, the state of the art recognizes the use of protection such as contraceptives *reduce the risk* of transmitting STDs; however even the “best means of protection” is not 100% effective and cannot not prevent the transmission of STDs. Thus, the likelihood of a topical composition, which is not considered the “best means of protection” to prevent the transmission of STDs, is highly unlikely.

Secondly, the state of art with regard to topical microbiocides specifically, indicates that the use of topical microbiocides in preventing STDs is “theoretically plausible, [but] scientists have not yet gathered data through clinical studies in humans to prove the concept valid”. See *Topical Microbiocides, Preventing Sexually Transmitted Diseases*, US Department of Health and Human Service (hereinafter as NIH document).

Thirdly, the state of the art indicates that the effectiveness of microbiocides is not predictable and *ex vivo* data is not necessarily indicative of *in vivo* performance:

In theory, creating an effective topical microbiocide should be easy. Simply identify chemicals that kill the disease-causing organisms, blend the chemicals with an inert gel or foam, and place it in the vagina. Experience, however, has shown that the simple approach may not work. The failure of the widely used contraceptive nonoxynol-9 (N-9) to prevent HIV transmission is a case in point. In both test-tube and animal experiments, N-9 appeared to prevent infection by HIV and animal experiments, N-9 appeared to prevent infection by HIV and other STD-causing microbes. Test in women, however, revealed that instead of preventing infections, frequent use of the detergent-like N-9 caused damage to cervical cells and actually increased the risk of HIV infection. See page 3.

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Lastly, Stone (Microbiocides: A New Approach to Preventing HIV and Other Sexually Transmitted Infections, Nature Reviews, Volume 1, December 2002) discloses substances including instant chlorhexidine and instant povidone iodine are still under investigation as potential microbiocides. See Table 1. Thus, the state of the art indicates that it has not been conclusively determined that the instantly claimed compounds are able to prevent the transmission of STDs.

Working Examples: All of the working examples provided by the specification are directed toward the inhibition of bacteria including *E. coli*, *Staphylococcus aureus*, *Candida albicans*, and *Neisseria gonorrhea*. These working examples provide *ex vivo* data on inhibition and not *in vivo* data. As discussed above, the state of the art clearly indicates that *ex vivo* results is not indicative of *in vivo* results.

The Amount of Experimentation Necessary: Firstly, the instant specification does not provide any guidance on the amount of the composition that must be administered to provide a sufficient coat on the penis or vagina to prevent transmission. Therefore, a skilled artisan would have to determine the effective amount to coat the penis or vagina sufficient to prevent any transmission of an STD. This would be a tedious and mostly likely unsuccessful process given the lack of guidance provided by the specification; the state of the art; and unpredictability of in the given art. Further, in order to practice the claimed scope of the invention, a skilled artisan would have to determine several factors associated with each STD prior to determining if the composition can prevent transmission the respective STD. For instance, NIH discloses that once a promising drug is found, preclinical rests must be done to demonstrate the safety and efficacy of the product and then human trials must be done in phases, usually three separate phases. NIH

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discloses that determining the effectiveness is difficult since the researchers must measure the continued absence of the diseases and confirm the trial intervention such as the microbiocide, and not other factors, is the responsible factor. See page 4. Thus, one must perform undue amount of experimentation required is an undue to practice the claimed scope of preventing transmission of STDs.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4, 6-8, 13-15, 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejected claims recite a preferable range of the component. For instance, claim 2 recites "wherein the amount of povidone-iodine complex used is preferably 10%", which is vague and indefinite since "preferably" language raises a question or doubt as to whether the feature introduced by such language is required. This is applicable to claims 3-4, 6-8, 13-15, and 17-19. The examiner suggests removing the phrase "preferably" to overcome this rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sackler et al (4,954,351) in view of Thompson (5,308,611) in view of Davis et al (2004/0068218) in further view of Mody et al (2003/0228376).

Sackler teaches a antiseptic composition and the method of making the composition which comprises 0.1-10% PVP-I (povidone-iodine) in water, an alcoholic solution, a soap, ointment gel, or suppository. See column 4, lines 20-35. The composition comprises PVP-I, free iodine wherein the source is from potassium iodine, and a source of iodate. The ratio of the iodine to iodate is 2:1 to 10:1. See column 3, lines 10-15. Potassium iodate is taught in an amount of 0.22-15%. Se column 3, lines 20-26. Sackler teaches the use of potassium iodate or potassium iodine depending on the iodine to iodide ratio desired. See example 1. Sackler teaches using citric acid and sodium phosphate to adjust the pH value to 5 to 6. See column 3, line 65 to column 4, line 2 and column 4, lines 55-60. Specifically example 6 teaches a composition comprising 10% PVP-I; 1% glycerol (polyhydric alcohol), 0.38% citric acid; 0.82% disodium hydrogen phosphate; 0.2% potassium iodate, sodium hydroxide, and water.

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Sackler does not teach chlorhexidine acetate in the composition. Although Sackler teaches adjusting the pH with buffering agents such as citric acid and phosphates, Sackler does not teach the instant concentration.

Thompson teaches an antiseptic composition and the method of making the composition which comprises chlorhexidine in a water-soluble form such as the gluconate, acetate, of hydrochloride salt form. See column 2, lines 15-25. The chlorhexidine salt is used in an amount of 0.05-25% and preferably 0.5-10%. See column 2, lines 60-65. The composition has a pH value of 5 to 7.5 and the pH is maintained using one or more buffers such as citric acid. See column 3, lines 49-55. The composition also contains an emollient such as glycerin (instant alcohol) in the amount of 1-10% depending on the desired softness. See column 3, lines 5-15.

Davis teaches a skin antiseptic composition and a dispenser. See abstract. The skin antiseptic composition comprises an antimicrobial agent including iodine complexes such as PVP-I; chlorhexidine or salts such as digluconate or diacetate; or combinations therefore. See [0042].

Mody et al teach a novel topical microbiocidal composition comprising povidone-iodine. See abstract. The composition may be used as a disinfectant. See [0023]. The composition has a pH of 5-6.5 and teaches the use of dibasic sodium phosphate in the amount of 2.5-5% and citric acid in the amount of 0.5-2% wherein the amount depends on the final pH desired. See [0052-0054].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Sackler and Thompson and additionally utilize chlorhexidine in the composition. One would have been motivated to do so since both Sackler's

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PVP-I composition and Thompson's chlorhexidine composition function as antiseptics and thus a skilled artisan would have reasonably expected an additive effect. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In *re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Further, Davis teaches and demonstrates the state of the art wherein it is known to an antiseptic composition that may comprise the specific combination of PVP-I and chlorhexidine (or its salts). Therefore, a skilled artisan would have been motivated to combine PVP-I and chlorhexidine acetate with a reasonable expectation of success. With regard to the recitation of 5-20% alcohol, a skilled artisan would have been motivated to increase the amount of glycerin from 1% taught in Sackler since Thompson teaches glycerin acts as an emollient in the amount of 1-10% and the concentration of glycerin depends on the desired softness. Therefore, a skilled artisan would have been motivated to manipulate the concentration of glycerin depending on the desired softness of the end product.

Secondly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further look to the teachings of Mody and manipulate the concentration of citric acid and sodium phosphate. One would have been motivated to do so since Mody teaches citric acid is usually utilized in an amount of 0.5-2% and phosphate buffers such as sodium phosphate are used in an amount of 2.5-5% to yield a pH between 5 to 6.5. Therefore, depending on the desired pH, one would have been motivated to manipulate the concentration of citric acid

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and the phosphate buffer accordingly. Further, a skilled artisan would have reasonably expected success since Mody teaches a microbiocidal composition that comprises PVP-I.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Sharmila S. Gollamudi
Examiner
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